1   **Behavior change theory, content and delivery of interventions to enhance adherence in chronic**

2   **respiratory disease: a systematic review**

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25   **Conflicts of interest**

26   The authors declare that they have no competing interests.

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28   **ABBREVIATIONS LIST**

29   BCT: behavior change technique

30   COPD: chronic obstructive pulmonary disease

31   CF: cystic fibrosis

32   IQR: interquartile range

33   MRC: medical research council

34   mRCT: metaregister of controlled trials

35   OSA: obstructive sleep apnea

36   Psych: psychologist

37   RT/PT: respiratory therapist/physical therapist

38   SD: standard deviation

39   SDM: shared decision making

40   SEM: standard error of the mean

41   TIDiER: template for intervention description and replication

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46   **ABSTRACT**

47   **Background:** We sought to describe the theory used to design treatment adherence interventions, the

48   content delivered, and the mode of delivery of these interventions in chronic respiratory disease.

49   **Methods:** We included randomized controlled trials of adherence interventions (compared to another

50   intervention or control) in adults with chronic respiratory disease (8 databases searched; inception until

51   March 2015). Two reviewers screened and extracted data: post-intervention adherence (measured

52   objectively); behavior change theory, content (grouped into psychological, education and self-

53   management/supportive, telemonitoring, shared decision-making); and delivery. "Effective" studies

54   were those with p<0.05 for adherence rate between groups. We conducted a narrative synthesis and

55   assessed risk of bias.

56   **Results:** 12,488 articles screened; 46 included studies (n=42,91% in OSA or asthma) testing 58

57   interventions (n=27, 47% were effective). Nineteen (33%) interventions (15 studies) used 12 different

58   behavior change theories. Use of theory (n=11,41%) was more common amongst effective interventions.

59   Interventions were mainly educational, self-management or supportive interventions (n=27,47%). They

60   were commonly delivered by a doctor (n=20,23%), in face-to-face (n=48,70%), one-to-one (n=45,78%)

61   outpatient settings (n=46,79%) across 2-5 sessions (n=26,45%) for 1-3 months (n=26,45%). Doctors

62   delivered a lower proportion (n=7,18% vs n=13,28%) and pharmacists (n=6,15% vs n=1,2%) a higher

63   proportion of effective than ineffective interventions. Risk of bias was high in >1 domain (n=43, 93%) in

64   most studies.

65   **Conclusions:** Behavior change theory was more commonly used to design effective interventions. Few

66   adherence interventions have been developed using theory, representing a gap between intervention

67   design recommendations and research practice.

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INTRODUCTION

Adherence, the extent to which patients' behaviors follow a recommended treatment path[1], is widely reported as being sub-optimal.[2] Chronic respiratory disease is no different – it is reported that between 30-50% of patients take treatment as prescribed.[3–5] This lack of adherence is not inconsequential; low adherence is associated with treatment failure and poor health outcomes.[5–7]

Many researchers have attempted to change adherence to prescribed treatments in chronic respiratory disease by developing behavior change interventions.[8–11] Medical Research Council (MRC) guidance states that these interventions should be developed systematically and involve the use of behavior change theories.[12] Yet studies of other complex interventions demonstrate that behavior change theories are rarely used.[12,13] The TIDieR reporting guidelines also recommend that the behavior change theory used to design the intervention should be reported alongside a detailed description of what was actually delivered (content) and how this was delivered (who provided the intervention, what was the mode of delivery, where was it delivered, in what frequency and over what duration).[14]

Systematic reviews of interventions to change adherence behavior in chronic respiratory disease have synthesised the evidence for the effectiveness of these interventions.[2,15] But they have not focused specifically on synthesising data on whether behavior change theories were used in their development, nor have they explored the content or the delivery of these interventions. These data are needed to inform the development of new interventions and to allow implementation of effective interventions into clinical practice. This systematic review describes the behavior change theories used to develop adherence interventions (compared to another intervention or usual care) in adults with chronic respiratory disease, the content that was delivered, along with who provided it, its mode of delivery, where it was delivered, in what frequency and over what duration.

MATERIALS AND METHODS

Inclusion and exclusion criteria for studies

We included randomized controlled trials (RCTs) of adults ≥ 18 years old, with a clinical diagnosis of chronic respiratory disease (asthma, bronchiectasis, chronic obstructive pulmonary disease [COPD], allergic bronchopulmonary aspergillosis, interstitial lung disease, obstructive sleep apnea [OSA][16] or cystic fibrosis [CF]) who received an adherence to treatment (any treatment with the exception of exercise) intervention compared to another intervention or usual care, where adherence was objectively

99   measured (e.g. electronic monitoring, pill counts or medication possession data). Only objective
100 measures of adherence were included because subjective adherence measurements (e.g. self-report
101 questionnaire) are known to over-estimate adherence.[17] Studies measuring adherence to exercise or
102 those available in abstract form only, were excluded. No attempt was made to identify unpublished
103 studies. This review was not registered on PROSPERO but the protocol can be obtained from the authors.
104 No ethical approval was required for this study.

Search strategy

106 We searched the Cochrane Central Register of Controlled Trials (CENTRAL), Medline, EMBASE, CINAHL,
107 International Pharmaceutical Abstracts, PsycINFO, Sociological abstracts and PEDro from inception until
108 March 2015 using the search strategy outlined in the online supplement. Language was restricted to
109 English. We searched the metaRegister of controlled trials (mRCT), ClinicalTrials.gov and the WHO trials
110 portal using the keywords 'adherence', 'compliance' and 'concordance.'

Study selection

112 Pairs of reviewers screened titles, abstracts and subsequent full texts (AMcC, CR, NY, CM, BON, JB, CH
113 plus three research assistants. All screeners received written instructions on screening from AMcC to
114 ensure consistency in approach (available on request from AMcC). Conflicts were resolved between
115 pairs and disagreements were resolved by a third reviewer (AMcC or CH).

Data extraction

117 Pairs of reviewers (AMcC and CR, NY and CM) extracted data on study design, participants and the
118 number of interventions tested (e.g. a three-arm study where two interventions were tested against
119 usual care would have two intervention arms). For each intervention, we extracted (from the abstract,
120 introduction, methods, results or discussion sections) the name of any behavior change theory used, the
121 content delivered, who provided the intervention, the mode of delivery, where it was delivered, in what
122 frequency and over what duration (items 2-8 of the TIDieR checklist[14]). Reviewers also extracted mean
123 (±SD, 95% CI or SEM) or median (IQR or range) and p values for objective adherence to treatment in
124 intervention and control groups at the end of study follow-up. If no other measures were reported,
125 mean change, mean difference (±SD) or the number of participants (%) categorized as adherent were
126 extracted. Pairs of reviewers (AMcC and CR, NY and CM) assessed each study's risk of bias (as high,
127 unclear or low, using the Cochrane Collaboration's tool for assessing risk of bias) across six domains:

128 random sequence generation, allocation concealment, blinding of participants and personnel, blinding
129 of outcome assessment, incomplete outcome data, and selective reporting.

130 **Synthesis of results and summary measures**

131 Included studies could not be meta-analysed due to heterogeneity in the outcome measures used and
132 the interventions tested. Without meta-analysis, we could not determine the statistical importance of
133 theory, content and delivery using meta-regression. Consequently, we narratively described the
134 behavior change theories used in intervention development, and provided descriptive statistics of what
135 content was delivered, who provided the intervention, what the mode of delivery was, where it was
136 delivered, in what frequency and over what duration. Classification of the content of complex
137 interventions is difficult, due to overlap in content between different interventions. However, we
138 grouped interventions by content (psychological; education and supportive or self-management;
139 telemonitoring; and shared decision-making interventions) by consensus within the research team.
140 More than one clinician may have delivered a single intervention; each profession is counted separately.
141 We categorized interventions into "effective" ($p<0.05$ for adherence rate between groups), or
142 "ineffective" ($p>0.05$) by whether they were associated with statistically significant improvements in
143 objective adherence.

144 **RESULTS**

145 **Summary of studies**

146 Screening resulted in the inclusion of 46 studies (Figure 1) testing 58 interventions in 12,415 participants
147 (median 100 per study, range 12-6431) (e-Table 1-3). Most studies included patients with OSA or asthma
148 (Figure 1). Twenty-seven interventions (47%) were shown to be effective (e-Table 4-6).

149 **Behavior change theory used in intervention development**

150 Most (n=39, 67%) interventions were not based on behavior change theory (Figure 2). Nineteen
151 interventions (33%) (from 15 studies) were designed using 12 different behavior change theories (Table
152 1). A higher proportion of effective interventions (n=11, 41%) used behavior change theory to design
153 their intervention than ineffective interventions (n=8, 26%) (Figure 3).

154 **Content**

155 Most (n=27, 47%) interventions delivered educational, self-management or supportive content (Figure
156 2). Educational, self-management or supportive content was more common for ineffective interventions
157 (n=17, 55%) than effective interventions (n=10, 37%) (Figure 3). Detailed descriptions of intervention
158 content are provided in eTable 1-3.

159 **Delivery**

160 The majority of interventions were delivered by doctors or nurses, on a face-to-face, one-to-one, out-
161 patient basis across two to five visits, at various frequencies over the course of one to three months
162 (Figure 2). Doctors delivered a lower proportion of effective interventions (n=7, 18%) compared to
163 ineffective (n=13, 28%). Pharmacists delivered a higher proportion of effective (n=6, 15%) compared to
164 ineffective interventions (n=1, 2%). No other differences could be identified in who provided the
165 intervention, the mode of delivery, where was it delivered, in what frequency and over what duration.

166 **Risk of Bias**

167 Three studies had a low risk of bias. We rated the remaining studies as having an unclear or high risk of
168 bias in one or more domains (high risk in ≥1 domains, n=28; unclear risk in ≥1 domains, n=43) (Figure 4,
169 e-Figure 1).

170

171 **DISCUSSION**

172 Most adherence interventions did not use behavior change theories in their development. Of those that
173 did, they used 12 different behavior change theories. Use of behavior change theory was more common
174 amongst effective interventions. Most adherence interventions used educational and self-management
175 or supportive interventions delivered on a face-to-face, one-to-one out-patient basis (up to five visits,
176 one to three months). Interventions with educational, self-management or supportive content
177 constituted over half of ineffective interventions. Doctors delivered a lower proportion of the effective
178 interventions, and pharmacists a higher proportion of effective interventions (compared to ineffective
179 interventions).

180 One third of studies reported using behavior change theories in their development and more studies in
181 the effective interventions group used behavior change theory, adding weight to the recommendations
182 to use behavior change theory to design interventions.[12] Our findings are limited by the small number of

183 studies that reported using theory, and the extent to which these theories were used to inform the

184 intervention is not known. Given the poor reporting noted in behavior change interventions, it is also

185 possible that more studies used theory but did not report it.[16] Only self-efficacy theory and social

186 cognitive theory were used in more than one study. This is not surprising, given the range of behavior

187 change theories that exist. At the time that many of these interventions were designed, there was no

188 clear cut way of defining which theories to use and how to use them. Michie and colleagues have

189 attempted to remedy this issue by creating the Theoretical Domains Framework, in which they have

190 combined 128 explanatory constructs from 33 behavior change theories into a single framework of 14

191 domains.[13,20]

192 Interventions using education, self-management or supportive approaches were more common

193 amongst ineffective interventions. The categories which were used to group content were broad and

194 the educational content varied greatly between studies, from group education[21] to patient advocates.[22]

195 Defining intervention content and grouping similar interventions is a common challenge when reviewing

196 behavior change interventions and is a limitation of this review. This is due to the variety of

197 interventions used and is, in part, due to poor reporting of the exact content of interventions.[23] The

198 Behavior Change Technique (BCT) Taxonomy (published after this review commenced) attempts to

199 overcome this issue by defining the individual components of behavior change interventions in a

200 reproducible way by providing definitions and examples.[24] It has been used in other systematic reviews

201 to extract the components of existing interventions.[25] The main challenge with using this approach is

202 that the original intervention content was not designed to be defined by behavior change techniques

203 and is so poorly reported that is makes it nearly impossible to use this approach.[25] Future adherence

204 intervention studies should describe their interventions using the BCT Taxonomy[24] and report them

205 using reporting checklists such as TIDiER and CONSORT.[14,26] Many studies in this review reported study

206 designs and outcomes poorly; the use of these checklists would also address these issues. An adherence

207 intervention for bronchiectasis has been developed using this approach, and is currently under further

208 development prior to feasibility and pilot testing.[27]

209 Findings from this review demonstrated that a higher proportion of effective interventions were

210 delivered by pharmacists, and a lower proportion by doctors. It is possible that pharmacists have more

211 time, and receive more training on how to monitor and change adherence behaviour, or that those

212 interventions led by pharmacists contained components that specifically targeted the underlying

213 barriers and facilitators to adherence. No other differences in delivery were identified. It is likely that

214   there is no 'one-size fits all' approach to intervention delivery and will depend on the healthcare context

215   in which the intervention is likely to be effective.[28] As an example, in cystic fibrosis, a group-based

216   primary care intervention delivered by a general practitioner and/or practice nurse is unlikely to be

217   effective given that most care is delivered by specialists in secondary care and patients are treated in

218   isolation of one another. In contrast, for COPD, this approach might be appropriate given that they

219   already receive annual reviews and have contact with their general practitioner and practice nurse (if in

220   the United Kingdom). Thus, researchers should involve stakeholders in intervention design to identify

221   the most appropriate delivery method for their patient population and healthcare context.[29]

222   Most studies in this review included those with OSA or asthma, making the findings more generalizable

223   to those populations. Clear gaps exist for patients with COPD, bronchiectasis and CF, who are known to

224   have low adherence.[5–7] Research is beginning to focus on developing adherence interventions for these

225   groups[27,30,31] and this is an area for further development.

226   Our data show that the education, self-management and supportive approaches that may be commonly

227   used in clinical practice may not always be effective at improving adherence, and that using theory-

228   based interventions may be more useful for clinicians to implement with patients.

229   Strengths of this review include: its broad scope, incorporating all adherence interventions across any

230   chronic respiratory disease or clinical setting, and the inclusion of studies reporting objective measures

231   of adherence. Comparisons between the use behavior change theory, content and delivery were

232   descriptive and based on small numbers of studies and should be interpreted with caution. The

233   heterogeneity of included interventions made categorization of intervention content problematic. We

234   only extracted data on adherence from final study visits, meaning any interim effects have not been

235   captured. Our search was restricted to English language and we did not contact authors to identify

236   unpublished studies, meaning the results presented could be affected by publication bias. We did not

237   extract any data on recruitment rates for individual studies which may affect the generalisability of the

238   findings presented.

239   **Conclusion**

240   Behavior change theory use was more common amongst effective interventions, providing evidence

241   that this in an important consideration for future adherence interventions. Few adherence interventions

242   have been developed using theory, representing a gap between medical research guidance and research

243   practice.

244

252 **Author's contributions**

253 All authors made substantial contributions to the conception or design of the work and interpretation of

254 the data. AMcC, CR, CH, JB, B'ON, NY, CM screened abstracts. AMcC, CR, NY and CM screened full text

255 and extracted data. AMcC, NY and CM analysed data. All authors contributed to the drafting and

256 revision of the manuscript for important intellectual content, and gave final of the version to be

257 published. All authors agree to be accountable for all aspects of the work in ensuring that questions

258 related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

259 AMcC had full access to all of the data in the study and takes responsibility for the integrity of the data

260 and the accuracy of the data analysis.

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FIGURE LEGENDS

Figure 1. PRISMA chart of review process

Figure 2. Summary of behavior change theory, content, and delivery of all interventions

SDM: shared decision making
RT/PT: respiratory therapist/physiotherapist
Psych: psychologist
Unknown: not reported in the manuscript
Numbers in bars denote percentage with each characteristic

Figure 3. Summary of behavior change theory, content, and delivery of effective and ineffective interventions

SDM: shared decision making
RT/PT: respiratory therapist/physiotherapist
Psych: psychologist
Unknown: not reported in the manuscript
Numbers in bars denote percentage with each characteristic

Figure 4. Summary of risk of bias of included studies

Table 1. Psychological theories used in the design of adherence interventions for OSA, asthma and COPD

Psychological theories used
Compliance therapy model[10]
Decisional balance[32]
Health Belief Model[33]
Horne and Weinman's Benefit-risk model[34]
Patient navigator model[22]
Prospect theory[35]
Protection motivation theory[36]
Self-efficacy theory[32,37]
Social cognitive theory[35,38,19,39,40]
Transtheoretical model[38]
Triandis theory of behavior[41]
"Theory-based" but specific theory not reported[42,43]